REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

Claims 1, 3, 5, 8, 14 and 15 are pending, of which claims 1, 8, and 14 are independent. The remaining claims have been canceled.

In the Office Action, claims 1, 3, 5, 8, 14 and 15 were rejected under Section 103(a) as obvious over Stevens (US 5,599,577), in view of Drug Launches (1993), Schmidt et al. (US 5,424,064) ("Schmidt ('064)"), Holtmann et al. ("Holtmann") and Gaginella et al., "Nitric Oxide as a Mediator of Disacodyl and Phenolphthalein Laxative action: Induction of Nitric Oxide Synthase," 270(3) Jl. Pharmacol. And Exp. Ther.," 1239 (1994)("Gaginella").

Applicants further wish to point out that claims 1, 3, 5, 8, 14 and 15 were allowed previously over Drug Launches (1993), Schmidt et al. (US 5,424,064) ("Schmidt ('064)"), and Holtmann et al. ("Holtmann") as set forth in the Notice of Allowability dated 11 June 2005 ("Notice").

The Rejection of Claims 1, 3, 5, 8, 14 and 15 under 35 U.S.C. §103(a) Over Stevens, in view of Drug Launches, Schmidt (064), Holtmann, and Gaginella Has Been Overcome

Claims 1, 3, 5, 8, 14 and 15 stand rejected under Section 103(a) as obvious over Stevens, in view of Drug Launches, Schmidt ('064), Holtmann, and Gaginella. Applicants respectfully disagree for the reasons that follow.

As set forth in the Notice, all of these claims were found to contain allowable subject matter over Drug Launches, Schmidt ('064), and Holtmann. Therefore, the only art that is newly cited in the Office Action but not in the Notice is Stevens and Gaginella. Applicants maintain that these references fail to disclose or suggest any additional subject matter that would render the present claims as unpatentable.

According to the Office Action, Stevens "disclose[s] the combination of simethicone... to a patient suffering from gas and a pharmaceutical suitable for treatment of gastrointestinal disorders." Stevens then particularly discloses pharmaceutical agents suitable for, for example, treating diarrhea. See Stevens, column 4, lines 51 - 67. However, Stevens fails to disclose or suggest the use of laxation agents or "small bowel motility agents," either alone or in combination with simethicone, let alone the particular combination of simethicone and bisacodyl as presently claimed. Stevens further fails to disclose or suggest an amount of bisacodyl that would be suitable for use in the invention as presently claimed.

Gaginella discloses that

> bisacodyl... act[s] on epithelial cells... and possibly smooth muscle cells to stimulate the release of NO[, nitric oxide]... The liberated NO may act on the epithelial cells to stimulate anion secretion and

> luminal fluid accumulation. Relaxation of the intestinal smooth muscle in concert with intraluminal fluid accumulation will lead to laxation or diarrhea, depending upon the dose of ... bisacodyl.

Gaginella, page 1243, column 2 (emphasis added). As a result of this hypothesized mechanism, Gaginella stated that as a result of stimulating nitric oxide gas production, "[b]isacodyl significantly... increased transit of the marker through the small intestine." See Gaginella, abstract and page 1242, column 1. However, Gaginella taught the use of 25 mg/kg of bisacodyl, which is significantly greater than the amount as claimed in claim 5. ("about 1 mg to about 15 mg [bisacodyl] per dose") In addition, Gaginella also failed to disclose or suggest the use of simethicone, either alone or in combination with an agent that increases intestinal transit, let alone the particular combination of simethicone with bisacodyl.

Applicants respectfully submit that one skilled in the art would not be motivated to combine the cited references as proposed in the Office Action. In particular, none of the cited prior art discloses or suggests that simethicone would act to stimulate the production of nitric oxide gas, which Gaginella hypothesizes is a contributor to bisacodyl's laxation and enhanced intestinal transit effects. See Gaginella, page 1243, column 2,. In fact, the prior art suggests quite the opposite. More specifically, the prior art acknowledged that simethicone would act in an opposite manner, e.g. as an agent that expels gas from the gut. (See, e.g., Holtmann, page 1646, column 1 ("simethicone... may accelerate the propulsion and expulsion of gas. As a result, the physiological gas load of the gut might be diminished.")(emphasis added)). Therefore, Applicants respectfully submit that one skilled in the art who reviewed the cited prior art would not be motivated to combine simethicone with bisacodyl because the prior art suggests that simethicone would act to accelerate the expulsion of gases from the intestine, and thus would have a negative effect on bisacodyl's proposed mechanism of action as provided in Gaginella.

Thus, in view of the above, Applicants respectfully submit that there is neither a disclosure nor a suggestion in the cited prior art to combine simethicone with bisacodyl or to use the resulting combination for purposes of, for example, improving small bowel motility. In fact, the cited references teach away from combining simethicone with bisacodyl. For these reasons, Applicants again submit that the claims are patentable. Early and favorable reconsideration is requested.

Respectfully submitted,
McNally, et al.

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